

EXHIBIT 15

RESEARCH



Accuracy of the Apple Watch Oxygen Saturation Measurement in Adults and Children with Congenital Heart Disease

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Abstract

As new customer health devices have been spread throughout the consumer market in recent years, it now needs to be evaluated if they also fulfill the requirements of clinical use. The Apple Watch Series 6 provides a new health feature with its oxygen saturation measurement. The aim of this prospective, investigator-initiated, single-arm study was to compare transcutaneous oxygen saturation measurements using the Apple Watch 6 with the conventional method of pulse oximetry in patients with congenital heart disease. Patients of any age presenting at the Leipzig Heart Center, Department for pediatric cardiology, were included. After obtaining informed consent, the routine oxygen saturation measurement with the pulse oximeter was taken and simultaneously three measurements with the Apple Watch. A total of 508 patients were enrolled. Comparing children and adults in terms of measurement success shows a statistically significant difference with a higher proportion of unsuccessful measurements in children, but no difference concerning correct versus incorrect Apple Watch measurements. Noticeable, strapping on the watch properly around the patient's wrists significantly improved the measurements compared to a watch only laid on. **The study demonstrated that oxygen saturation measurement with the Apple Watch 6 is not yet up to the medical standard of pulse oximetry, too large a proportion of the measurements remain either unsuccessful or incorrect.** While a high proportion of unsuccessful measurements in children can be attributed to movement, the cause in adults usually remains unclear. Further influencing factors on a correct, or successful measurement could not be found.

Keywords Apple Watch · Smart watch · Pediatric cardiology · Telemedicine · Oxygen saturation

Introduction

Today multiple physiological parameters can be monitored by new customer health devices, for example, smartwatches. While these devices for measuring vital parameters—such as heart rate, respiratory rate, oxygen saturation, and many more—have been remarkably spread throughout the consumer market within the last few years, it now needs to be evaluated if they also fulfill the requirement of clinical and medical use.

Originally developed as watches for sports and physical activity, the devices were primarily intended to provide a better overview of one's own fitness and general physical well-being. Yet, the measured vital parameters may also be used as progression parameters of disease. A daily or continuous measurement using a smartwatch would thus be a cleverly devised way of long-term monitoring of patients with chronic disease. However, this raises the question of the accuracy and reliability of the devices.

In the case of the Apple Watch, some revolutionary health functions have been developed in recent years—the iECG

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& oxygen saturation measurement are to be mentioned as milestones.

While the iECG function has already proven itself in a medical context and is now approved as a medical product by the FDA [1], the benefits of oxygen saturation measurement in everyday medical use still need to be proven. Especially since Apple refers to the following on its website: “Blood Oxygen app measurements are not intended for medical use, including self-diagnosis or consultation with a doctor, and are only designed for general fitness and wellness purposes” [2, 8].

Nevertheless, oxygen saturation is an important parameter for checking respiratory and circulatory function and is therefore particularly important for patients with cardiac, pulmonary, or hematological pre-existing conditions who could gain a health benefit from independently verifiable daily measurements.

This study focuses on oxygen saturation measurement in patients with congenital heart disease. The oxygen saturation is a main monitoring parameter and drives therapeutic decisions, especially in young children with complex congenital heart disease (i.e. Tetralogy of Fallot, univentricular hearts after surgical shunt formation, etc.). Optimal timing of interventional or surgical therapy is partly dependent on oxygen saturation levels in these patients, therefore the monitoring of the saturation level is extremely important.

Smartwatches could thus help to better monitor the health of patients with congenital heart defects and provide valuable information to the treating physicians. In addition, treatment adjustments could be initiated quickly without delay until the next visit. Ambulatory ergometry checks could be reduced by smartwatch monitoring throughout the day with its all-embracing situations such as periods of stress, physical activity, and also sleep-associated conditions.

This study aimed to compare transcutaneous oxygen saturation measurements using the Apple Watch Series 6 with the conventional method of pulse oximetry in patients with congenital heart disease including very low oxygen saturation levels.

Methods

This prospective, investigator-initiated, single-arm study aimed to assess the diagnostic accuracy of the oxygen saturation measurement using the Apple Watch Series 6 in children and adults with congenital heart disease.

Study Population

Patients of any age presenting for outpatient or inpatient treatment at the Leipzig Heart Center, Department for pediatric cardiology, were eligible to participate regardless of their cardiac history. Hemodynamically unstable

patients and patients with severe dys-/amelias symptoms were not enrolled.

All participants had to give their informed consent to participate in the study. For children under 18 years of age, at least one parent had to give consent. If the consent was withdrawn later, the respective participants were excluded from the study.

Regarding their diagnoses, the study population was classified into patients with congenital heart disease requiring surgery and those without. Patients with congenital heart disease requiring surgery were further subdivided into surgically corrected, surgically palliated, and uncorrected patients. Examples of the respective subgroups are listed below.

Congenital Heart Disease Requiring Surgery

Corrective Surgery

- Transposition of the great arteries (TGA) →arterial switch operation; Rastelli
- Tetralogy of Fallot→curative surgery
- Atrial septal defect (ASD)
- Ventricular septal defect (VSD) } →pericardial patch
plastic or direct suture
- Simple atrioventricular septal defect
- Patent ductus arteriosus→ligation
- Coarctation of the aorta→aortal reconstruction
- Valve defects→valve reconstruction or replacement
- Pulmonary stenosis/RVOT obstruction→pericardial dilatation plastic

Palliation

Heart defects where biventricular correction was not possible.

- Transposition of the great arteries →Senning procedure; Mustard procedure
- Mitral/tricuspid atresia
- Single ventricle (HLHS/HRHS) } →Fontan procedure
- Complex atrioventricular septal defect

uncorrected:

anatomical heart defects that have not yet been corrected, i.e. mainly infants who have not yet undergone required surgery.

or.

adults who have never had surgical correction (e.g. hemodynamically relevant unclosed septal defects).

Others

- All initial presentations for clarification
- Cardiac arrhythmias, also including those treated with pacemaker or ablation
- Genetic diseases requiring cardiological control (e.g. Marfan syndrome, HOCM, HCM)
- Hemodynamically insignificant defects (e.g. small PFO, restrictive VSD, etc.)
- Valve defects (mild to moderate)—not yet requiring intervention
- Ballooned/transarterially stented stenoses
- Congenitally corrected transposition of the great arteries (ccTGA)

Technical Background

Both measuring devices—pulse oximeter and Apple Watch—are used to determine the percentage of oxygenated hemoglobin in the arterial blood.

As oxygenated hemoglobin (HbO_2) shows a different absorption curve than deoxygenated hemoglobin (Hb)— HbO_2 shows a significantly lower absorption than Hb at a wavelength of approx. 680 nm, and higher absorption than Hb at longer wavelengths of approx. 800 nm and upwards—the percentage of oxygenated blood can be measured via LEDs with different wavelengths. In the pulse oximeter used in everyday clinical practice these LEDs are on one side of the pulse oximeter finger clip, and a sensor (a photodiode), measuring the absorbed light components, on the opposite side. The pulse oximeter then determines the proportion of oxygenated hemoglobin in the total hemoglobin and finally displays the calculated value as oxygen saturation. The following applies:

$$\text{SpO}_2 = \text{HbO}_2 / (\text{HbO}_2 + \text{Hb})$$

The values measured with the pulse oximeter serve as a reference and were considered the gold standard in this study.

The Apple Watch Series 6 uses the same physical principles. The difference to the finger clip pulse oximeter is that the measurement is made via reflection. Four LED clusters are built into the back of the smartwatch, which emit green, red, and infrared light. By using three different wavelengths, an attempt is made to compensate for natural color differences in the skin and thus improve accuracy. In addition, there are also four photodiodes in the base of

the watch's housing, which detect the proportion of light rays reflected from the arterial blood. Unlike the pulse oximeter, the light transmitter and receiver are therefore on the same side. The Apple Watch Blood Oxygen App then calculates the oxygen saturation based on the measured proportion of the reflected light of the different wavelengths. Apple specifies a measurable range of 70–100% of oxygen saturation [3].

Measurements

All pulse oximetry measurements set as the gold standard were performed using the GE Healthcare (GE Medical Systems Information Technologies, Inc, 8200 Tower Avenue, Milwaukee, Wisconsin USA) Carescape Dinamap V100 pulse oximeter. To guarantee an accurate measurement, there are different sized "fingerlings" connectable to the pulse oximeter depending on the size and thickness of a finger. For participants weighing less than 10 kg, the Nellcor (Tyco Healthcare Group LP, Nellcor Puritan Bennett Division Pleasanton, CA USA) P/I wrap sensor was used; for participants weighing more than 10 kg, the Masimo (Masimo Corporation, 52 Discovery, Irvine, CA USA) LNCS-DCI finger clip sensor was used. Both sensors have the same good reliability.

After obtaining consent, participants were advised to sit or lay down in a comfortable position, stop moving and breathe spontaneously. The routine oxygen saturation measurement with the pulse oximeter was taken and simultaneously also three measurements of each 15 s with the smartwatch placed on the patient's wrist of the same arm, using the built-in sensors of the smartwatch (Apple Watch Series 6, Apple Inc., Cupertino, California) with a market version of the blood oxygen application (see Fig. 1). If the first measurement with the Apple Watch was not successful, the watch was moved slightly for measurement two and three.

At the beginning of the study, it was planned to place the Apple Watch only loosely on the patients' wrists, for the sake of ease of use. After 259 participants however, it was decided, if possible, to tie the watch firmly around the wrist from now on. For this purpose, we used an adjustable elastic wristband made of rubber, which enabled a good and tight fit in almost all participants, even young children. The only group in which the smartwatch was manually attached were newborns and babies, because their wrists were partially too thin even for the elastic wristband.

In addition, other parameters were collected in this second half of the survey, such as skin temperature, skin dryness, and unsuccessful measurements due to movement.

All blood oxygen recordings were saved in a digital format and served as references in our study. Saved formats



Fig. 1 Blood oxygen acquisitions [8]

were transferred to the Telemonitoring Center (Helios Cloud) for further analysis and processing.

Statistics

Statistical analysis was performed using SPSS 28 and Microsoft Excel. Pulse oximeter and Apple Watch measurements were compared using Bland–Altman Plots, bivariate Pearson correlation, and linear regression analysis, with a p value of <0.05 considered statistically significant.

To generate one comparative value to the pulse oximeter value for the analysis, the mean was calculated out of all successful Apple Watch measurements (maximum out of three). Since the smartwatch-measured values of one person were sometimes very far apart, it was decided to only include those means into the analyses regarding correct versus incorrect measurements where the difference between the individual Apple Watch measurements was only a maximum of 4 percentage points—e.g., three successful measurements with 93%, 97% and 95%. The other cases with a measurement difference ≥ 4 percentage points were evaluated as not usable and therefore false, as they cannot be considered reliable in everyday life—e.g., two successful measurements with 92% and 99%. If there was only one successful measurement, it was scored the same as the mean of two or three successful measurements (with measurement difference ≤ 4 percentage points). In the analysis of successful versus unsuccessful Apple Watch measurements all cases were included equally.

Results

Patient Characteristics

A total of 508 patients were enrolled. Of these, 270 children and 238 adults. Their characteristics are listed in Tables 1 and 2.

As listed above, all participants were classified according to their heart disease. Table 3 shows the proportional distribution in children and adults.

Technical Aspects

The technical recording of the oxygen saturation value with the Apple Watch Series 6 could not be achieved in all participants even with triple measurement. The proportion of successful and unsuccessful measurements is reported in Table 4, Fig. 2.

Differences between the success of measurements in children and adults were checked with the Pearson Chi-square test. With $p=0.019$ (asymptotic significance, bivariate) a significant difference could be seen, indicating that measurement successfulness is lower in children—even if the effect size of $\Phi=-0.104$ is only small [4].

Table 5 shows the data on the reproducibility of Apple watch measurements and correlation to the gold standard pulse oximeter, separately for @1 (first measurement with the Apple Watch), @2 (second measurement with the Apple Watch), and @3 (third measurement with the Apple Watch).

Table 1 Characteristics of the 270 participating CHILDREN (< 18 years age)

	Median	Range	Min–Max
Age (years)	10	16.9	0.1–17
Body height (cm)	141	139.8	51–190.8
Body weight (kg)	33.2	146.5	3.5–150
BMI (kg/m ²)	17.1	35	10.8–45.8
BMI (z) ^a	−0.2	10.2	−6.1 to 4.1
Cardiac EF ^b	66	49	40–89
Blood pressure systolic	112	104	69–173
Blood pressure diastolic	60	62	37–99
SpO ₂ (pulse oximeter) ^c	97	27	73–100

^aChildren's standardized Z-score for body mass index^bCardiac ejection fraction^cBlood oxygen saturation measured with the pulse oximeter**Table 2** Characteristics of the 238 participating ADULTS

	Median	Range	Min–Max
Age (years)	32	58	18–76
Body height (cm)	170	55	143–198
Body weight (kg)	73.8	81.6	39–120.6
BMI (kg/m ²)	25	33.2	13.8–47
Cardiac EF ^b	62	63	25–88
Blood pressure systolic	126	105	96–201
Blood pressure diastolic	66	46	51–97
SpO ₂ (pulse oximeter) ^c	97	22	78–100

^aChildren's standardized Z-score for body mass index^bCardiac ejection fraction^cBlood oxygen saturation measured with the pulse oximeter

Figures 3 and 4 visualize the comparison of the Apple Watch measurement method with that of the pulse oximeter. Only those cases where the three Apple Watch

measurements are not more than 4 percentage points apart are considered.

Looking separately at the measurement series @1, @2, and @3, the proportion of correct measurements is always between 80 and 90% for both children (Table 6) and adults (Table 7).

All cases with at least one successful Apple Watch measurement were included in the Pearson Chi-square test to evaluate a difference between children and adults concerning correct versus incorrect Apple Watch measurements. With $p=0.847$ (asymptotic significance, bivariate) there is no significant difference, meaning that the watch works equally well for children and adults.

As these results were only partially satisfactory after 259 patients measured with a laid-on Apple Watch, it was then decided to tie the watch properly around the patients' wrists from now on—at least whenever possible. In some cases, especially newborns, the watch could not be tied around due to a disproportionate wrist-to-watch ratio.

Table 8. The correlation coefficient, considering only those 221 cases where the Apple Watch was properly tied around the wrist.

Figures 5 and 6 clearly illustrate the better measuring success as well as more correct measurement results with the Apple Watch properly tied around the patients' wrist. This applies equally to children and adults and is statistically significant at a Pearson Chi-Q (asymptotic significance, bivariate) < 0.001. With $\Phi=0.348$, a moderate effect size can be assumed according to Jacob Cohen [4].

Further possible influencing factors—cardiac anatomy, cardiac ejection fraction, blood pressure, BMI, skin temperature, and skin dryness—could not provide significant results in the multivariate test and thus have no significant influence on a correct Apple Watch measurement.

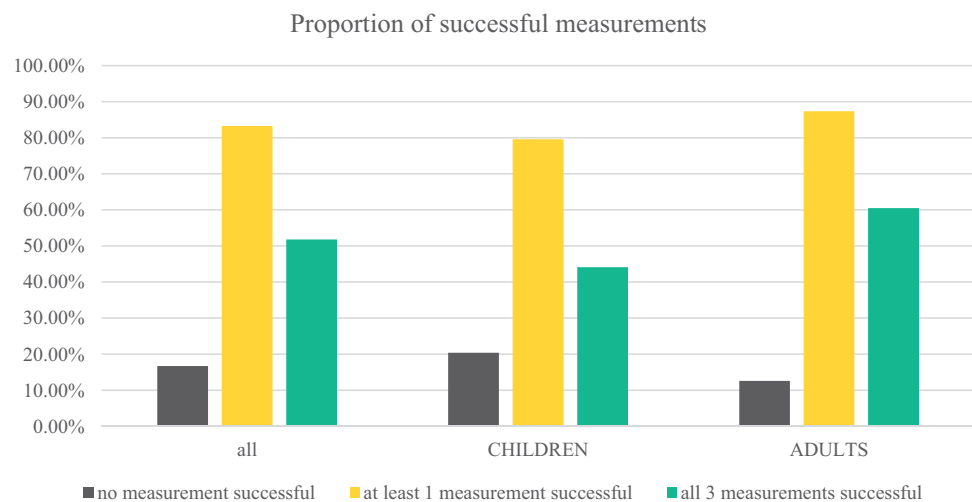
As described above, from half of the participants onwards, attention was paid to whether an unsuccessful measurement was due to wobbles or small patient movements. A total of

Table 3 Proportional distribution of heart disease in children and adults

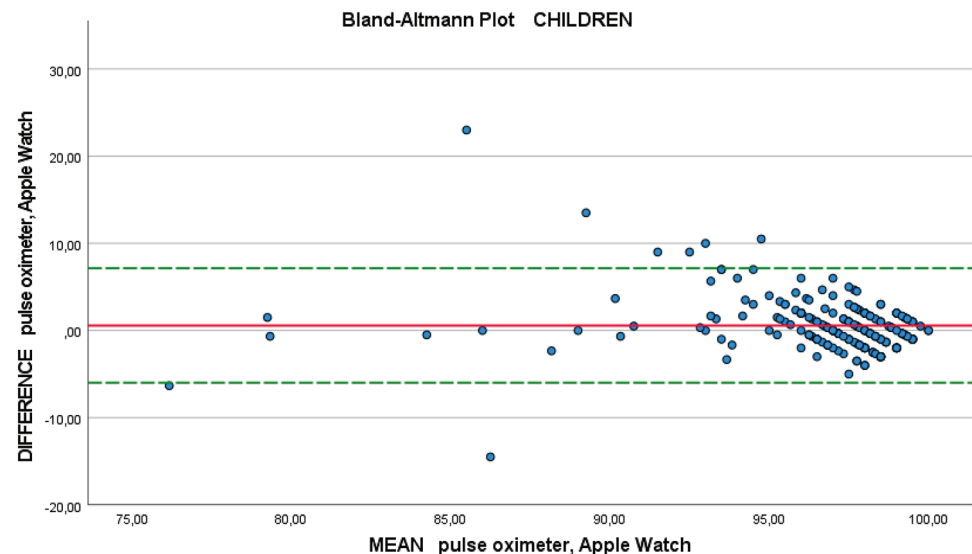
Type of surgery	Anatomical heart defects requiring surgery						Others	
	Corrected		Palliated		Uncorrected			
Children	72	27%	31	11%	30	11%	137	51%
Adults	131	55%	30	13%	12	5%	65	27%

Table 4 Proportion of successful & unsuccessful measurements with the Apple Watch 6

	All		Children		Adults	
No measurement successful	85	17%	55	20%	30	13%
At least 1 measurement successful	423	83%	215	80%	208	87%
All 3 measurements successful	263	52%	119	44%	144	61%
Total	508	100%	270	100%	238	100%

Fig. 2 Proportion of successful & unsuccessful measurements with the Apple Watch 6**Table 5** Correlation of Apple Watch measurements to the pulse oximeter (all cases)

		tcO ₂ pulse oximeter	tcO ₂ @1	tcO ₂ @2	tcO ₂ @3	mean
tcO ₂ pulse oximeter	Pearson- correlation	1	0.657	0.665	0.666	0.663
	Significance (bivariate)		<0.001	<0.001	<0.001	
	Cases	508	326	368	366	

Fig. 3 Bland-Altman Plot for children

249 participants were therefore screened. Figures 7 and 8 visualize the respective proportions for children and adults.

Of all study participants, a total of 24 patients had a pulse oximetrically measured oxygen saturation <90%, including 10 children and 14 adults. Only in half of these patients, the Apple Watch measured correctly. In five of the cyanotic patients, none of the three Apple Watch measurements was successful, including three adults (ages 24, 38, 50 years) and two children (ages 12, 15 years). Regarding the cyanotic

patients below 1 year of age (five in total), at least two measurements were successful in each case (Table 9).

Given that in 5 of the 24 cyanotic patients all three Apple Watch measurements were unsuccessful, only 19 cases could be expected in this sample. The Fisher's exact test was therefore used to match the incorrectly versus correctly measured cyanotic patients. With $p=0.077$ (exact significance two-sided according to Fisher), no difference could be found between cyanotic and non-cyanotic patients regarding a correct versus an incorrect Apple Watch measurement.

Fig. 4 Bland-Altman Plot for adults**Table 6** Proportion of correct & incorrect measurements in children

	@ 1		@ 2		@ 3		Mean
Correctly measured ^a	136	89%	156	84%	151	81%	85%
Incorrectly measured ^b	16	11%	29	16%	35	19%	15%
Overall successful	152	100%	185	100%	186	100%	100%
Out of 270 children							

^aMeans maximum 3 percentage points ($\leq 3\%$) difference from gold standard pulse oximeter value^bMeans more than 3 percentage points ($> 3\%$) difference from gold standard pulse oximeter value**Table 7** Proportion of correct & incorrect measurements in adults

	@ 1		@ 2		@ 3		Mean
Correctly measured ^a	146	84%	152	83%	152	84%	84%
Incorrectly measured ^b	28	16%	31	17%	28	16%	16%
Overall successful	174	100%	183	100%	180	100%	100%
Out of 238 adults							

^aMeans maximum 3 percentage points ($\leq 3\%$) difference from gold standard pulse oximeter value^bMeans more than 3 percentage points ($> 3\%$) difference from gold standard pulse oximeter value**Table 8** Correlation of Apple Watch measurements to the pulse oximeter (considering only those cases with the watch tied around the wrist)

		tcO ₂ pulse oximeter	tcO ₂ @ 1	tcO ₂ @ 2	tcO ₂ @ 3	Mean
tcO ₂ pulse oximeter	Pearson- correlation	1	0.825	0.802	0.813	0.813
	Significance (bivariate)		<0.001	<0.001	<0.001	
	cases	221	193	195	184	

To check the measurement consistency of the Apple Watch, 30 patients were measured twice on two different days. In 25 patients (83%), the smartwatch measured correctly on both days.

Discussion

After other Apple Watch products, such as the iECG, were able to deliver very good results in studies [5, 6] great expectations were placed on the latest Apple Watch

Fig. 5 Proportion of measurement success with the watch laid on vs. tied around in children

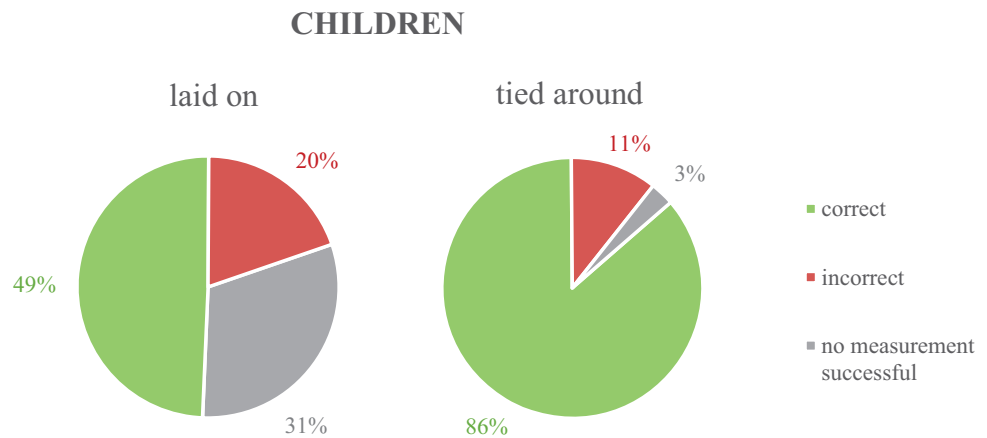


Fig. 6 Proportion of measurement success with the watch laid on vs. tied around in adults

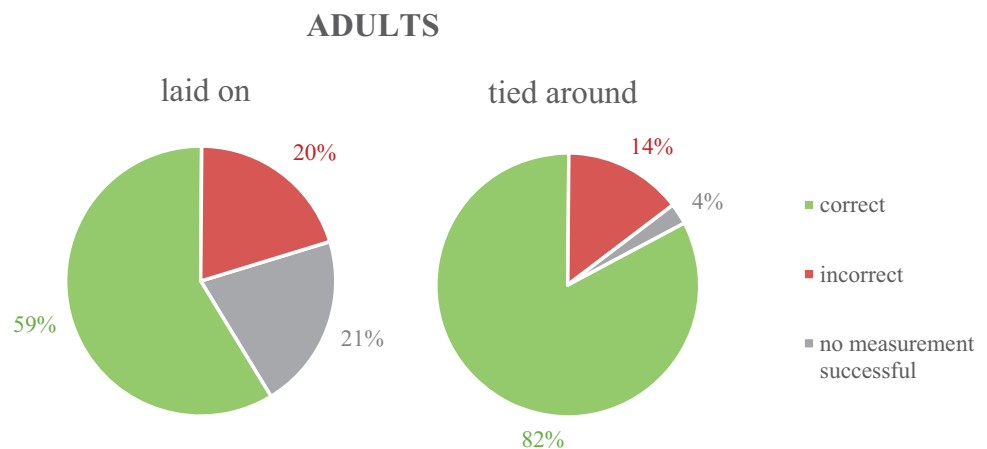
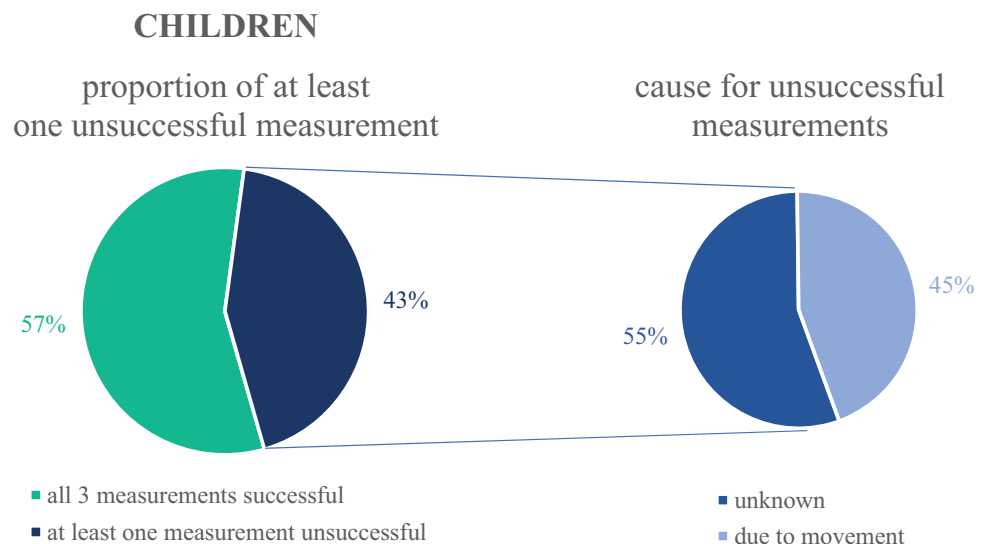
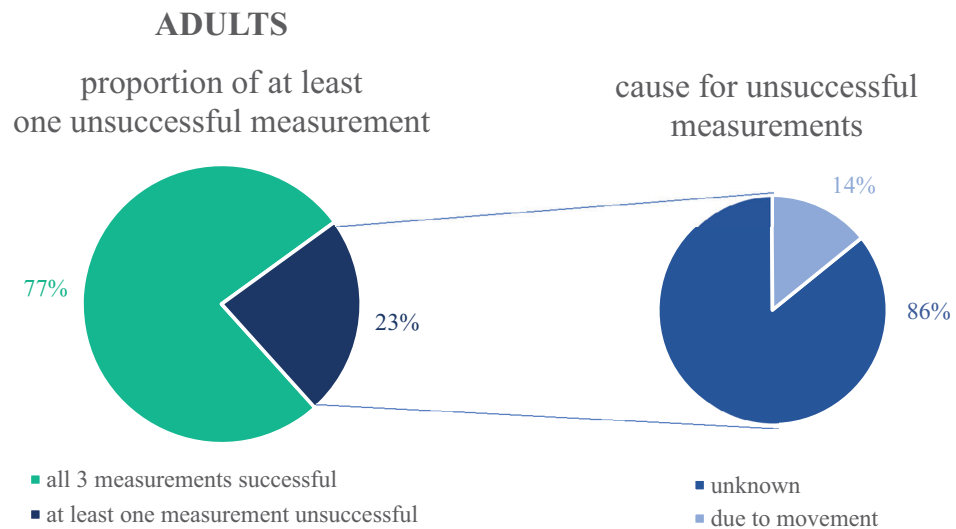


Fig. 7 Cause for unsuccessful measurements in children



application—the oxygen saturation measurement. According to Apple, the app is suitable for people aged 18 years and older and for a saturation range of 70–100% [2, 8]. Having already collected data for adults with lung disease [7], this study was the first to investigate the functionality

of the Apple Watch oxygen saturation measurement in children and adults with congenital heart disease—a patient group that, along with lung disease patients, would benefit most from a mobile event monitor to detect drops in saturation.

Fig. 8 Cause for unsuccessful measurements in adults**Table 9** Proportion of measurements in cyanotic patients

	All		Children		Adults	
Correctly measured	12	50%	6	60%	6	43%
Incorrectly measured	7	29%	2	20%	5	36%
No measurement successful	5	21%	2	20%	3	21%
Total	24	100%	10	100%	14	100%

This study demonstrates though, that the current reliability is too low for medical purposes even if the Apple Watch can measure correctly in certain patients.

Looking at the participants altogether, it is noticeable that the first measurement @1 was more often unsuccessful than @2, and @3 in both children and adults. A possible conclusion is that if the Apple Watch measurement is primarily unsuccessful, at least a second measurement attempt should be performed with a slightly different position of the watch. If the second attempt is also unsuccessful, then the watch is probably not working well for this person. However, the proportion of correct measurements out of all successful ones remained the same in the measurement series @1, @2 and @3. It can thus be concluded that people for whom the watch can measure successfully do not seem to achieve an improvement in measurement results through multiple recordings.

Remarkably, there were no differences in the measurement correctness between children and adults ($p > 0.05$). Even though the Bland–Altman–Plots for children show more extreme outliers and a wider range of variation, the proportion of correct measurements is very similar in both groups (Table 6, 7).

However, when comparing children and adults in terms of measurement success, there is a statistically significant difference ($p < 0.05$). The higher proportion of unsuccessful measurements in children is most likely mainly due to

movement artifacts and poor wrist immobilization. The Apple Watch is very susceptible to wobbling and must be held extremely still for a successful measurement, which is sometimes difficult even for adults. Furthermore, it should be considered that all participants were measured with an adult-sized Apple Watch of height 44 mm, width 38 mm, depth 10.7 mm [2, 8]. Due to children's smaller wrists and the resulting smaller contact surface of the watch on the skin, higher scattered radiation must be assumed for the children's measurements. This may have had an influence on both the success and the accuracy of a measurement.

Table 8 demonstrates that tying the Apple Watch around the patient's wrist will certainly produce more reliable values, but the proportion of incorrect measurements remains high. It is nevertheless noticeable that the measurement results of the participants, who have had the Apple Watch tied around their wrists are much better than those with the watch only laid on. The probability of a correct measurement is about three times higher with a tied-on watch. Furthermore, a much higher correlation between pulse oximeter and Apple Watch measurement can be observed when considering only those cases where the Apple Watch was properly tied around the wrist (Pearson correlation coefficient = 0.81). This could also be due to a lower proportion of scattered radiation, as when the watch is laid on, the sensor surface in the back of the watch's case may not lie completely on the skin. In addition, a properly tied round watch reduces

the brightness around the sensor and thus also the proportion of other, distorting wavelengths—like the effect of the finger clip on the pulse oximeter. Because there were proportionately more cases of children with a watch only laid on, this may explain the differences in the Bland–Altman-Plots between children and adults.

Since such a significant improvement in the results could be achieved solely by changing the haptic application of the watch, it can be speculated that technical changes in the watch or case design could allow valid measurements in the future. Especially a smaller Apple Watch model could improve measurements in children, as a better ratio between sensor and wrist size could result.

For the other influencing factors of cardiac anatomy, ejection fraction, blood pressure, BMI, skin temperature, and skin dryness collected in this study, no significant impact on a correct Apple Watch measurement could be demonstrated. With most study participants having warm skin temperature and normal skin dryness, the proportion of patients with cold and dry or sweaty skin was correspondingly low, possibly too low for reliable statistical analysis. Besides, in "Comparison of SpO₂ and heart rate values on Apple Watch and conventional commercial oximeters devices in patients with lung disease", no statistically significant influence on the Apple Watch measurement could be found for the parameters skin color, wrist circumference, and the presence of hair on the wrist [7].

The initial impression that the Apple Watch measures less exactly in cyanotic patients could not be substantiated statistically, as there was no significant difference in measurement accuracy between cyanotic and non-cyanotic patients ($p > 0.05$). This may be due to the small sample size of only 19 successfully measured cyanotic patients. Since the Apple Watch is advertised as a health product for monitoring their own fitness and wholesomeness, it would be an advantage, especially for cyanotic heart and lung patients if the watch could also measure reliably in the lower saturation range.

Looking at the sample with the double measured patients, it must first be noted that all the 30 participants have had at least one successful measurement on both days. This group therefore only included patients for whom the watch measured quite successfully. The proportion with a correct measurement on two different days was ~83% and thus corresponds approximately to the general probability of a correct value with a successful measurement (Table 6, 7). Yet, an incorrect measurement on the first day does not predict an incorrect measurement on the second day and vice versa. Therefore, it remains questionable whether a good future functionality can be directly inferred after a value has been measured correctly once.

A smartwatch that can measure oxygen saturation in addition to other medical parameters would be a useful everyday aid, especially for heart patients. The Apple Watch Series 6

marks the beginning of this. With some technical improvements, such as lower susceptibility to tiny wobbles or a smaller model for children, valid measurements could possibly be made in the future, and a future clinical relevance similar to the iECG could also be expected.

Conclusion

The study demonstrates that oxygen saturation measurement with the Apple Watch Series 6 is not yet up to the medical standard of the pulse oximeter. Strapping on the watch significantly improved the measurements, but still, too large a proportion of the measurements remain either unsuccessful or incorrect. While a high proportion of unsuccessful measurements in children can be attributed to movement, the cause in adults usually remains unclear. Further influencing factors on a correct, or successful measurement could not be found. The application can still provide a personal benefit for some patients to monitor their own blood oxygen levels. Future technical improvements of the device may impact the clinical significance of this measurement tool.

Limitations

This study is limited because of its single-center design.

Author Contributions CP study design and conduction, critical revision of manuscript. CP study conduction and paper draft.

Declarations

Competing interests The authors declare no competing interests.

References

1. Wuerthele M (2017). *First FDA-certified Apple Watch accessory is AliveCor's Kardia Band EKG meter*. <https://appleinsider.com/articles/17/11/30/alivecor-kardia-band-ekg-meter-is-the-first-fda-certified-apple-watch-peripheral>. Accessed 5 Nov 2021
2. Ed. Apple (2021). *How to use the Blood Oxygen app on Apple Watch Series 6 or Series 7*. <https://support.apple.com/en-us/HT211027>. Accessed 5 Nov 2021
3. Ed. Apple (2020). *Apple Watch Series 6 delivers breakthrough wellness and fitness capabilities*. <https://www.apple.com/newsroom/2020/09/apple-watch-series-6-delivers-breakthrough-wellness-and-fitness-capabilities/>. Accessed 5 Nov 2021
4. Cohen J (1988) *Statistical power analysis for the behavioral sciences*. Taylor & Francis Ltd, Milton Park
5. M Kobel KP (2021). *Accuracy of the Apple Watch iECG in children with and without congenital heart disease*. <https://pubmed.ncbi.nlm.nih.gov/34468775/>. Accessed 6 Nov 2021

6. Amirali Behzadi AS (2020). *Feasibility and reliability of Smart-Watch to obtain 3-lead electrocardiogram recordings*. <https://pubmed.ncbi.nlm.nih.gov/32906661/>. Accessed 6 Nov 2021
7. Leonardo Zumerkorn Pipek RF (2021). *Comparison of SpO₂ and heart rate values on Apple Watch and conventional commercial oximeters devices in patients with lung disease*. <https://pubmed.ncbi.nlm.nih.gov/34556765/>. Accessed 6 Nov 2021
8. Ed. Apple (2021). *Apple Watch Series 6—technical specifications*. https://support.apple.com/kb/SP826?viewlocale=en_US&locale=de_CH. Accessed 5 Nov 2021

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